HERMETIC PACKAGES AND FEEDTHROUGHS FOR NEURAL PROSTHESES

Quarterly Progress Report # 6

(Contract NIH-NINCDS-N01-NS-4-2319)

(Contractor: The Regents of the University of Michigan)

For the Period:

January-March 1996

Submitted to the

Neural Prosthesis Program
National Institute of Neurological Disorders and Stroke
National Institutes of Health

By the

Center For Integrated Sensors and Circuits
Department of Electrical Engineering and Computer Science
University of Michigan
Ann Arbor, Michigan 48109-2122

Program Personnel:

UNIVERSITY OF MICHIGAN
Professor Khalil Najafi: Principal Investigator
Graduate Student Research Assistants:
Mr. Anthony Coghlan: RF Telemetry & Microstimulator Assembly
Mr. Mehmet Dokmeci: Packaging and Accelerated Testing
Mr. Mark Nardin: Microstimulator Circuit Design/Fabrication
Mr. Jeffrey Von Arx: Electrode and Package Fabrication/Testing

VANDERBILT UNIVERSITY
Professor David L. Zealear, Principal Investigator

April 1996

This QPR is being sent to you before it has been reviewed by the staff of the Neural Prosthesis Program.

SUMMARY

During the past quarter we continued testing of glass packages under accelerated conditions, performed more detailed testing of the single-channel microstimulator in preparation for its manufacture and delivery to outside users, provided package substrates for animal testing, and started the fabrication of a new run of silicon substrates for use in future package testing.

Our most significant package testing results to date are those obtained from a series of silicon-glass packages that have been soaking in DI water at 85°C and 95°C for more than a year. We reported in the last progress report that the last package that was soaking at 95 °C had failed. There were also 4 packages that were soaking at 85°C. All these four packages are still dry and under test. Of the original 10 packages, the longest going sample has reached a maximum of 594 days. We have calculated a worst case mean time to failure of 301.4 days for the samples at 85°C (assuming that all failed today), and of 119 days for the samples soaking at 95°C. The worst case MTTF at body temperature based on these tests is 167 years. The activation energy is calculated to be about 1.06eV. These tests have been very encouraging and clearly indicate the packages can last for many years in aqueous environments.

In addition to these tests in DI water, we also continued soaking the new ultrasonically-machined glass capsules in ***saline*** at the above two temperatures. These new glass capsules were bonded to thick silicon substrates. We had started soaking a total of 28 packages in the previous quarter, namely 17 at 85°C and 11 at 95°C. Out of these 11 packages that were tested at 95°C all had failed before the beginning of this quarter. From the 17 packages that were started at 85°C, we had 6 dry packages at the beginning of this quarter. Out of these 6 packages, 4 of them failed during the various stages of this quarter. The remaining 2 are still being tested. These 2 devices have been tested for a total of 242 days and 192 days and are still dry. Packages that were soaked at 95°C all failed at various points in time, exclusively due to corrosion and dissolution of the polysilicon bonding layer in saline. Nonetheless, we have calculated an average lifetime of about 38 days for these preliminary soaks at 95°C, and 89.6 days at 85°C. Using these values, one can calculate a MTTF of about 33 years at 37°C. As mentioned above, the primary problem with some of these soak tests in saline at 95°C is dissolution of the deposited thin films. We will continue to conduct additional tests to acquire more reliable data in saline and eliminate this problem. To do this, new silicon substrates are being fabricated. The fabrication has taken longer than anticipated due to equipment downtime, but is near completion within the next few weeks. The new substrates will be used for testing at elevated temperatures with appropriate polymers deposited over the sensitive films to slow down the dissolution process.

We also have had 4 packages soaking at room temperature in saline. The longest lasting package has been soaking for 495 days, and an average soak period of 421 days for all packages at room temperature. We will continue to observe these packages for any sign of leakage.

In-vivo tests on a few of the packages were performed by Dr. James Walter at the Hines VA Hospital. Seven packages were implanted into the bladder wall of rats and explanted after one month. The preliminary indication from these tests is that both the packages and the host tissue survived extremely well. Our examination of the explanted packages has not shown any damage to the package, nor any sign of leakage into the package. We will continue to conduct additional in-vivo tests on these packages.

Finally, we continued our testing and characterization of microstimulators. Several of the factors affecting the operation of the microstimulator inside the full volume of a 9cm coil have now been identified. We are currently redesigning both the transmitter and the receiver to ensure proper operation under all conditions. Meanwhile, we have prepared several microstimulators that will be encapsulated with silicone and will be soon released for electrical testing in biological environments.

1. INTRODUCTION

This project deals with the development of hermetic, biocompatible micropackages and feedthroughs for use in a variety of implantable neural prostheses for sensory and motor handicapped individuals. The project also aims at continuing work on the development of a telemetrically powered and controlled neuromuscular microstimulator for functional electrical stimulation. The primary objectives of the project are: 1) the development and characterization of hermetic packages for miniature, silicon-based, implantable three-dimensional structures designed to interface with the nervous system for periods of up to 40 years; 2) the development of techniques for providing multiple sealed feedthroughs for the hermetic package; 3) the development of custom-designed packages and systems used in chronic stimulation or recording in the central or peripheral nervous systems in collaboration and cooperation with groups actively involved in developing such systems; and 4) establishing the functionality and biocompatibility of these custom-designed packages in *in-vivo* applications. Although the project is focused on the development of the packages and feedthroughs, it also aims at the development of inductively powered systems that can be used in many implantable recording/stimulation devices in general, and of multichannel microstimulators for functional neuromuscular stimulation in particular.

Our group here at the Center for Integrated Sensors and Circuits at the University of Michigan has been involved in the development of silicon-based multichannel recording and stimulating microprobes for use in the central and peripheral nervous systems. More specifically, during the past two contract periods dealing with the development of a single-channel inductively powered microstimulator, our research and development program has made considerable progress in a number of areas related to the above goals. A hermetic packaging technique based on electrostatic bonding of a custom-made glass capsule and a supporting silicon substrate has been developed and has been shown to be hermetic for a period of at least a few years in salt water environments. This technique allows the transfer of multiple interconnect leads between electronic circuitry and hybrid components located in the sealed interior of the capsule and electrodes located outside of the capsule. The glass capsule can be fabricated using a variety of materials and can be made to have arbitrary dimensions as small as 1.8mm in diameter. A multiple sealed feedthrough technology has been developed that allows the transfer of electrical signals through polysilicon conductor lines located on a silicon support substrate. Many feedthroughs can be fabricated in a small area. The packaging and feedthrough techniques utilize biocompatible materials and can be integrated with a variety of micromachined silicon structures.

The general requirements of the hermetic packages and feedthroughs to be developed under this project are summarized in Table 1. Under this project we will concentrate our efforts to satisfy these requirements and to achieve the goals outlined above. There are a variety of neural prostheses used in different applications, each having different requirements for the package, the feedthroughs, and the particular system application. The overall goal of the program is to develop a miniature hermetic package that can seal a variety of electronic components such as capacitors and coils, and integrated circuits and sensors (in particular electrodes) used in neural prostheses. Although the applications are different, it is possible to identify a number of common requirements in all of these applications in addition to those requirements listed in Table 1. The packaging and feedthrough technology should be capable of:

1- protecting non-planar electronic components such as capacitors and coils, which typically have large dimensions of about a few millimeters, without damaging them;
2- protecting circuit chips that are either integrated monolithically or attached in a hybrid fashion with the substrate that supports the sensors used in the implant;
3- interfacing with structures that contain either thin-film silicon microelectrodes or conventional microelectrodes that are attached to the structure;

Table 1: General Requirements for Miniature Hermetic Packages and Feedthroughs for Neural Prostheses Applications

Package Lifetime:

$\geq$ 40 Years in Biological Environments @ 37°C

Packaging Temperature:

$\leq$360°C

Package Volume:

10-100 cubic millimeters

Package Material:

Biocompatible

Transparent to Light

Transparent to RF Signals

Package Technology:

Batch Manufactureable

Package Testability:

Capable of Remote Monitoring

In-Situ Sensors (Humidity & Others)

Feedthroughs:

At Least 12 with $\leq$125μm Pitch

Compatible with Integrated or Hybrid Microelectrodes

Sealed Against Leakage

Testing Protocols:

In-Vitro Under Accelerated Conditions

In-Vivo in Chronic Recording/Stimulation Applications

We have identified two general categories of packages that need to be developed for implantable neural prostheses. The first deals with those systems that contain large components like capacitors, coils, and perhaps hybrid integrated circuit chips. The second deals with those systems that contain only integrated circuit chips that are either integrated in the substrate or are attached in a hybrid fashion to the system.

Figure 1 shows our general proposed approach for the package required in the first category. This figure shows top and cross-sectional views of our proposed approach here. The package is a glass capsule that is electrostatically sealed to a support silicon substrate. Inside the glass capsule are housed all of the necessary components for the system. The electronic circuitry needed for any analog or digital circuit functions is either fabricated on a separate circuit chip that is hybrid mounted on the silicon substrate and electrically connected to the silicon substrate, or integrated monolithically in the support silicon substrate itself. The attachment of the hybrid IC chip to the silicon substrate can be performed using a number of different technologies such as simple wire bonding between pads located on each substrate, or using more sophisticated techniques such as flip-chip solder reflow or tab bonding. The larger capacitor or microcoil components are mounted on either the substrate or the IC chip using appropriate epoxies or solders. This completes the assembly of the electronic components of the system and it should be possible to test the system electronically at this point before the package is completed. After testing, the system is packaged by placing the glass capsule over the entire system and bonding it to the silicon substrate using an electrostatic sealing process. The cavity inside the glass package is now hermetically sealed against the outside environment. Feedthroughs to the outside world are provided using the grid-feedthrough technique discussed in previous reports. These feedthroughs transfer the electrical signals between the electronics inside the package and various elements outside of the package. If the package has to interface with conventional microelectrodes, these microelectrodes can be attached to bonding pads located outside of the package; the bond junctions will have to be protected from the external environment using various polymeric encapsulants. If the package has to interface with on-chip electrodes, it can do so by integrating the electrode on the silicon support substrate. Interconnection is simply achieved using on-chip polysilicon conductors that make the feedthroughs themselves. If the package has to interface with remotely located recording or stimulating electrodes that are attached to the package using a silicon ribbon cable, it can do so by integrating the cable and the electrodes again with the silicon support substrate that houses the package and the electronic components within it.

Figure 2 shows our proposed approach to package development for the second category of applications. In these applications, there are no large components such as capacitors and coils. The only component that needs to be hermetically protected is the electronic circuitry. This circuitry is either monolithically fabricated in the silicon substrate that supports the electrodes (similar to the active multichannel probes being developed by the Michigan group), or is hybrid attached to the silicon substrate that supports the electrodes (like the passive probes being developed by the Michigan group). In both of these cases the package is again another glass capsule that is electrostatically sealed to the silicon substrate. Notice that in this case, the glass package need not be a high profile capsule, but rather it need only have a cavity that is deep enough to allow for the silicon chip to reside within it. Note that although the silicon IC chip is originally 500μm thick, it can be thinned down to about 100μm, or can be recessed in a cavity created in the silicon substrate itself. In either case, the recess in the glass is less than 100μm deep (as opposed to several millimeters for the glass capsule). Such a glass package can be easily fabricated in a batch process from a larger glass wafer.

Figure 1: A generic approach for packaging implantable neural prostheses that contain a variety of components such as chip capacitors, microcoils, and integrated circuit chips. This packaging approach allows for connecting to a variety of electrodes.

We believe the above two approaches address the needs for most implantable neural prostheses. Note that both of these techniques utilize a silicon substrate as the supporting base, and are not directly applicable to structures that use other materials such as ceramics or metals. Although this may seem a limitation at first, we believe that the use of silicon is, in fact, an advantage because it provides several benefits. First, it is biocompatible and has been used extensively in biological applications. Second, there is a great deal of effort in the IC industry in the development of multi-chip modules (MCMs), and many of these efforts use silicon supports because of the ability to form high density interconnections on silicon using standard IC fabrication techniques. Third, many present and future implantable probes are based on silicon micromachining technology; the use of our proposed packaging technology is inherently compatible with most of these probes, which simplifies the overall structure and reduces its size.

Once the above packages are developed, we will test them in biological environments by designing packages for specific applications. One of these applications is in recording neural activity from cortex using silicon microprobes developed by the Michigan group under separate contracts. The other involves the chronic stimulation of muscular tissue using a multichannel microstimulator for the stimulation of the paralyzed larynx. This application has been developed at Vanderbilt University. Once the device is built, it will be used by our colleagues at Vanderbilt to perform both biocompatibility tests and functional tests to determine package integrity and suitability and device functionality for the reanimation of the paralyzed larynx. The details of this application will be discussed in future progress reports.

Figure 2: Proposed packaging approach for implantable neural prostheses that contain electronic circuitry, either monolithically fabricated in the probe substrate or hybrid attached to the silicon substrate containing microelectrodes.

2. ACTIVITIES DURING THE PAST QUARTER

2.1 Hermetic Packaging

Over the past few years we have developed a bio-compatible hermetic package with high density, multiple feedthroughs. This technology utilizes electrostatic bonding of a custom-made glass capsule to a silicon substrate to form a hermetically sealed cavity, as shown in Figure 3. Feedthroughs are obtained by forming closely spaced polysilicon lines and planarizing them with LTO and PSG. The PSG is reflowed at 1100°C for 2 hours to form a planarized surface. A passivation layer of oxide/nitride/oxide is then deposited on top to prevent direct exposure of PSG to moisture. A layer of fine-grain polysilicon (surface roughness 50Å rms) is deposited and doped to act as the bonding surface. Finally, a glass capsule is bonded to this top polysilicon layer by applying a voltage of 2000V between the two for 10 minutes at 320 to 340°C, a temperature compatible with most hybrid components. The glass capsule can be either custom molded from Corning code #7740 glass, or can be batch fabricated using ultrasonic micromachining of #7740 glass wafers.

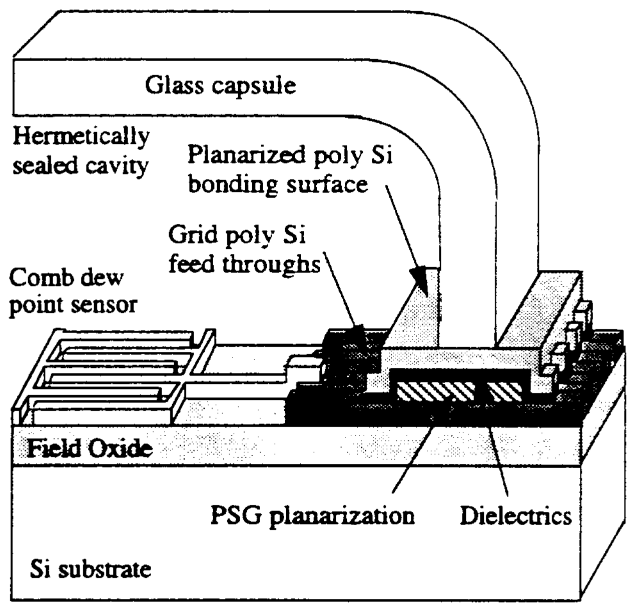

Figure 3: The structure of the hermetic package with grid feedthroughs.

During the past year we have electrostatically bonded and soak tested over one hundred and sixty of these packages. The packages successfully prevent leakage in soak tests at 95°C for over 4 months on average and at 85°C for almost 10 months in deionized water. The bonding yield has varied between 85% to 72% (yield is defined as the percentage of packages which last more than 24 hours soaking in DI water), and preliminary in-vivo tests indicate that the package is bio-compatible and rugged. Our earlier accelerated tests which are the 85°C and the 95°C tests in deionized water and the room temperature tests in phosphate buffered saline are performed with thinned silicon substrates (thinned down to about 150μm) using the custom molded glass capsules made from Corning code #7740 glass. The more recent accelerated tests, namely the 85°C and 95°C tests in phosphate buffered saline, are performed on packages made with the silicon substrates having full thickness (about 500μm) and ultrasonically micromachined glass capsules made of #7740 glass wafers. We will report on the status of all the ongoing tests in the following sections.

2.1.1 Accelerated Soak Tests With The New Ultrasonically Machined Glass Capsules

We have continued our accelerated soak tests on the ultrasonically machined glass packages this quarter. In our past progress report we mentioned that we had been soaking a total of 28 packages, namely 17 at 85°C and 11 at 95°C. Out of these 11 packages that were tested at 95°C all had failed before the beginning of this quarter. From the 17 packages that were started at 85°C, we had 6 dry packages at the beginning of this quarter. Out of these 6 packages, 4 of them failed during the various stages of this quarter. The remaining 2 are still being tested. These 2 devices have been tested for a total of 242 days and 192 days and are still dry. At this point in time, we have 6 samples that have lasted longer than 100 days in saline solution at 85°C. Tables 2 and 3 below list some other pertinent data from these soak tests. Figure 4 summarizes the final results from the 85°C soak tests and the Figure 5 summarizes the results obtained so far from the 95°C soak tests. The figures show a best curve fit to our lifetime data that illustrates the general trend. All of the packages that have leaked have been carefully analyzed both under a optical microscope and also under a scanning electron microscope to identify the reasons for the failures. We report on these observations in the Failure Analysis section of this report.

Table 2: Key data for 85°C soak tests in saline.

Number of packages in this study	17
Soaking solution	Saline
Failed within 24 hours (not included in MTTF)	3
Packages lost due to mishandling	0
Longest lasting packages so far in this study	242 days
Packages still under tests with no measurable room temperature condensation inside	2
Average lifetime to date (MTTF)	*89.6 days*

Table 3: Key data for 95°C soak tests in saline.

Number of packages in this study	11
Soaking solution	Saline
Failed within 24 hours (not included in MTTF)	5
Packages lost due to mishandling	0
Longest lasting packages so far in this study	70 days
Packages still under tests with no measurable room temperature condensation inside	0
Average lifetime to date (MTTF)	*38 days*

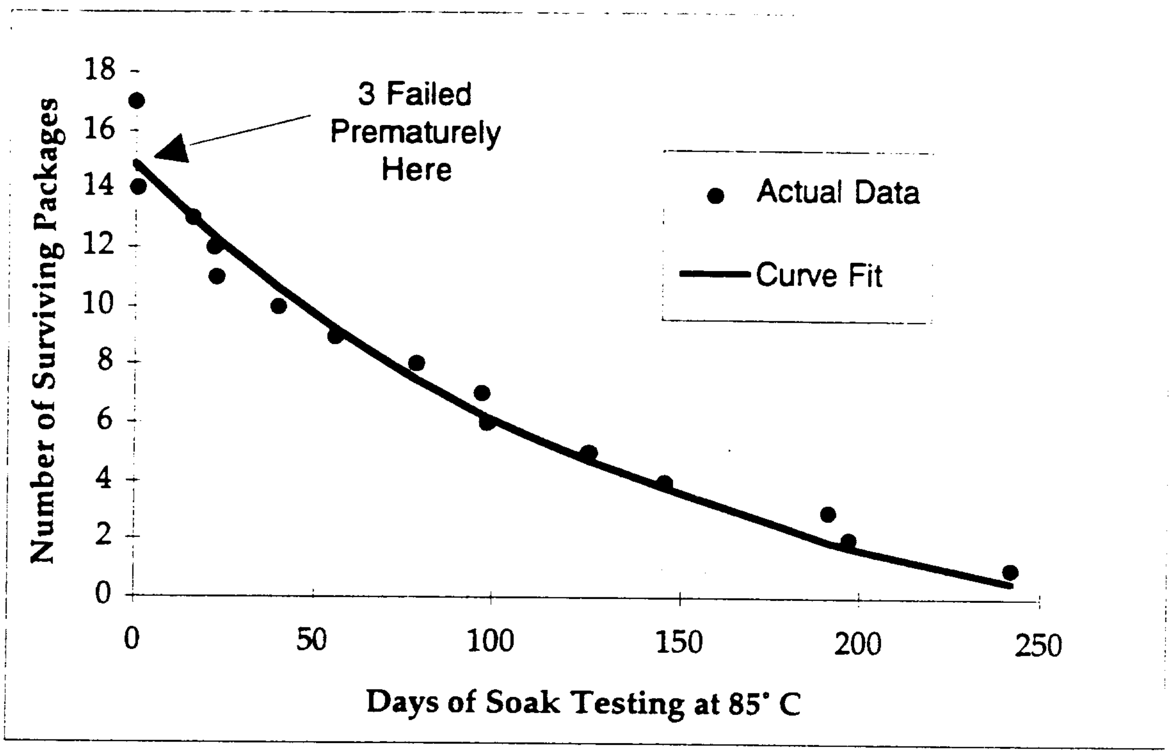

Figure 4: Summary of the lifetimes of the 17 packages which have been soak tested at 85° C.

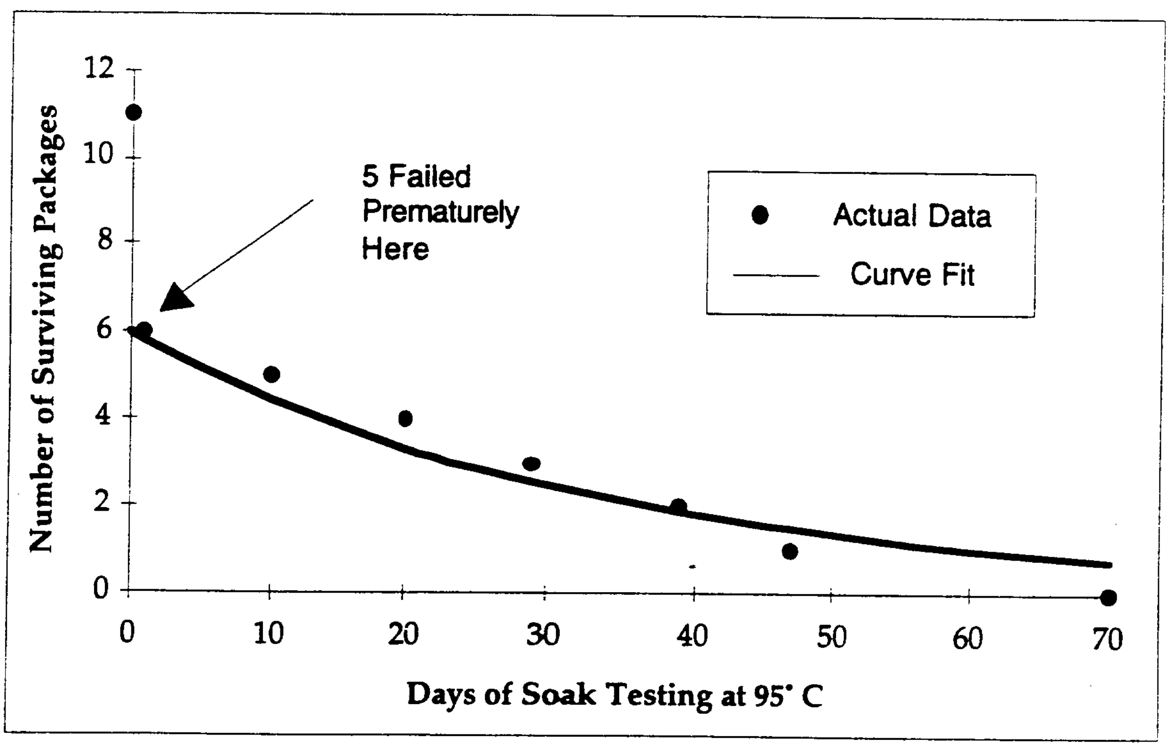

Figure 5: Summary of the lifetimes of the 11 packages which have been soak tested at 95° C.

The packages in these accelerated tests have been monitored every few days for room temperature condensation both electrically by means of an integrated dew point sensor and also visually by the aid of a microscope. We define failure as room temperature condensation. With these ultrasonically machined packages, due to their flat top surface, we have the additional advantage of being able to monitor their bonding surface for discoloration and dissolution. In order to reduce dissolution related failures, we have been refreshing the saline solution of the packages on a daily basis. We also have started a new fabrication run for the silicon packaging substrates. These substrates have better surface planarity than the previous ones and as such would be less prone to the effects of dissolution and hence should stay hermetic for longer periods. The fabrication process has passed the deposition of passivation layers. We expect to finish this run as soon as possible and then start new tests at 3 different temperatures. These new tests will supply us with additional information about the longevity of the package in saline.

2.1.2 Interpretation of the Long Term Soak Testing Results in Saline

Generally during accelerated testing, one models the mean time to failure (MTTF) as an Arrhenius processes (In the VLSI industry this model is used for failure due to diffusion, corrosion, mechanical stress, electromigration, contact failure, dielectric breakdown, and mobile ion/surface inversion). The generalized equation used in all these cases is given below where MTTF is the mean time to failure, A is a constant, ξ is the stress factor other than temperature, (such as pressure or relative humidity), n is the stress dependence, Q is the activation energy, K_B is Boltzman's constant, and T is the temperature in Kelvin.

$$MTTF = A \cdot \xi^{-n} \cdot e^{\left(\frac{Q}{K_B T}\right)}$$

For the accelerated soak tests that we have performed on the packages, there was no stressing factor other than temperature, so the ξ term drops out of the above equation. The resulting equation can be rewritten as a ratio of MTTFs as it is below. This is the model we are using to interpret the accelerated soak tests.

$$AF = \frac{MTTF_{Normal}}{MTTF_{Accelerated}} = e^{\frac{Q}{K_B}\left(\frac{1}{T_{Normal}} - \frac{1}{T_{Accelerated}}\right)}$$

By using the current MTTFs at 85° C and 95° C, we can easily calculate the activation energy (Q) and from this activation energy we can proceed to obtain an acceleration factor (AF) for these tests, and then calculate the MTTF at body temperature. Since the tests in 85° C are still in progress we cannot accurately determine the activation energy in our tests. Also until all of the samples show leakage, we cannot obtain the MTTF at the accelerated temperatures. We can, however, obtain worst case MTTFs for the 85° C soak tests by assuming that all the remaining packages in this test show leakage today. This worst case MTTF can be used to calculate the worst case activation energy, and hence the worst case MTTF at body temperature. Performing this calculation yields:

$$MTTF|_{85°C} = 89.6\,Days \quad MTTF|_{95°C} = 38\,Days$$

Q=0.974eV, AF(95°C)=313, AF(85°C)=132.6

$$MTTF|_{37°C} = 32.6\ Years$$

We call this average lifetime at body temperature of 32.6 years the worst case lifetime because every extra day that the remaining 85° C packages last increases this projected lifetime. Moreover, this lifetime is very close to our final lifetime mainly because there is only 2 packages that are still going from a total of 28 packages. We will update these results during the next progress report. Moreover, the above activation energy of 0.974eV is about what we expect for these packages. For comparison, corrosion is known to be one of the major failure mechanisms for plastic-encapsulated silicon chips, and the activation energy for corrosion of these standard plastic packages is well characterized and known to be about 0.7 to 0.9 eV. It should be noted that the above activation energy is consistent with values obtained in our previous tests. Furthermore, this activation energy is greatly effected by the dissolution rate of the deposited films, and as such is not necessarily indicative of the actual activation energy. We plan on conducting additional tests so that we can extract out the actual activation energy independent of the dissolution effects. This will only improve the activation energy, which in turn will increase the MTTF at body temperature.

2.1.3 Ongoing Accelerated Soak Tests of Old Packages in Deionized Water

We have continued accelerated soak testing of the packages made from the molded glass capsules this quarter, and 20% of the packages in these tests have now surpassed one and a half years of accelerated testing still showing no signs of leakage. Similar to the tests in saline, we are using temperature as the acceleration factor because it is an easy variable to control, and because moisture diffusion is a strong (exponential) function of temperature. We have been soaking 10 samples each at 95° C and 85° C in this series of tests. Tables 4 and 5 list some pertinent data for these soak tests. Figure 6 summarizes the final results from the 95° C soak tests and Figure 7 summarizes the results so far from the 85° C tests. These figures also list the causes of failure for individual packages when it is known, and they show a curve fit to our lifetime data to illustrate the general trend. The curve fit, however, only approximates the actual package lifetimes since some of our packages failed due to breaking during testing rather than due to leakage.

At the beginning of this quarter, we had 4 packages that were being tested in deionized water at 85°C. These 4 packages still show no indication of moisture tested both electrically with the dew point sensors and also visually with the aid of a microscope. Of the original 10 packages, the longest going sample has reached a maximum of 594 days. Currently, 4 packages that have lasted more than 500 days and all are being tested. We have calculated a worst case mean time to failure of 301.4 days for the samples at 85°C (assuming that all failed today). The mean time to failure is 119 days for the samples soaking at 95°C. Since some of the samples have been accidentally dropped during the initial phases of our testing, we exclude these samples while calculating the mean time to failures.

2.1.4 Interpretation of the Long Term Soak Testing Results in Deionized Water

Similar to the model we have used in our accelerated soak tests in saline, one models the mean time to failure (MTTF) as an Arrhenius process. The generalized equation use in all these cases is the same as given above. One can calculate the activation energy and the MTTFs at the two testing temperatures and then calculate the MTTF at body temperature.

Table 4: Key data for 95°C soak tests in DI water.

Number of packages in this study	10
Soaking solution	DI water
Failed within 24 hours (not included in MTTF)	1
Packages lost due to mishandling	2
Longest lasting packages in this study	484 days
Packages still under tests with no measurable room temperature condensation inside	0
Average lifetime to date (MTTF) including losses attributed to mishandling	*118.7 days*
Average lifetime to date (MTTF) not including losses attributed to mishandling	*135.7 days*

Table 5: Key data for 85°C soak tests in DI water.

Number of packages in this study	10
Soaking solution	DI water
Failed within 24 hours (not included in MTTF)	2
Packages lost due to mishandling	3
Longest lasting packages so far in this study	594 days
Packages still under tests with no measurable room temperature condensation inside	4
Average lifetime to date (MTTF) including losses attributed to mishandling	*301.4 days*
Average lifetime to date (MTTF) not including losses attributed to mishandling	*466.4 days*

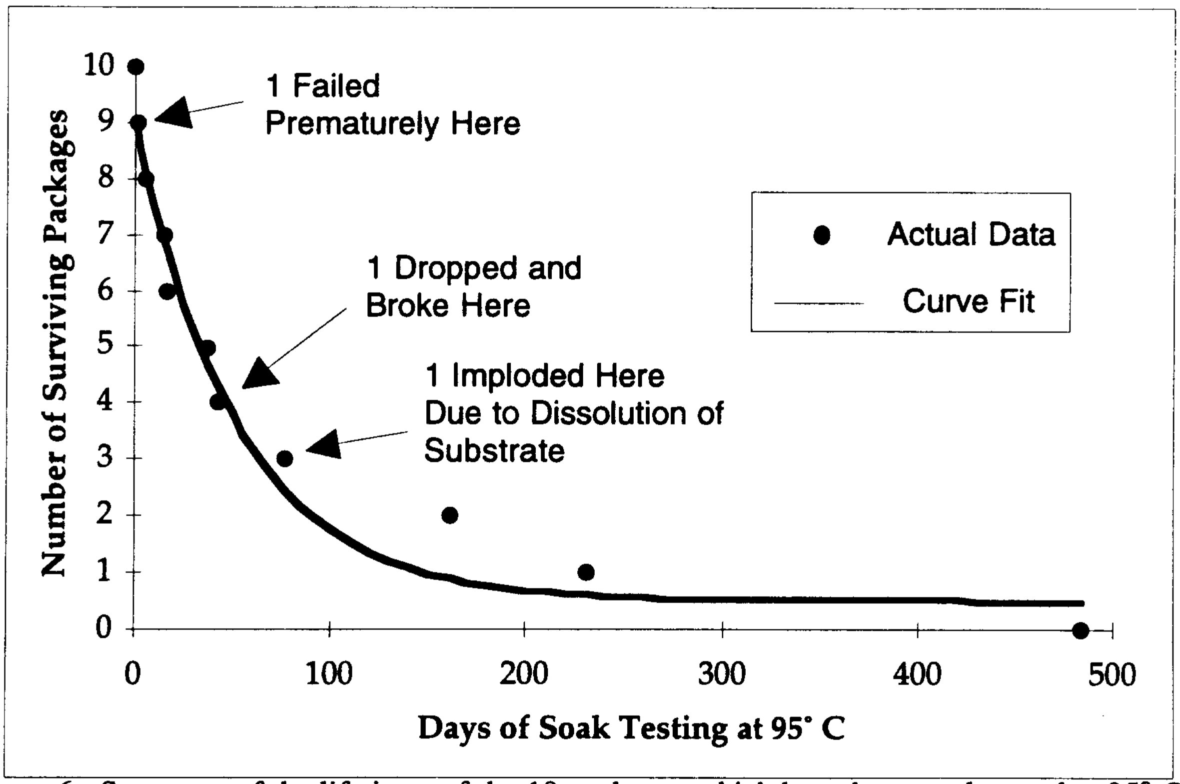

Figure 6: Summary of the lifetimes of the 10 packages which have been soak tested at 95° C in DI water.

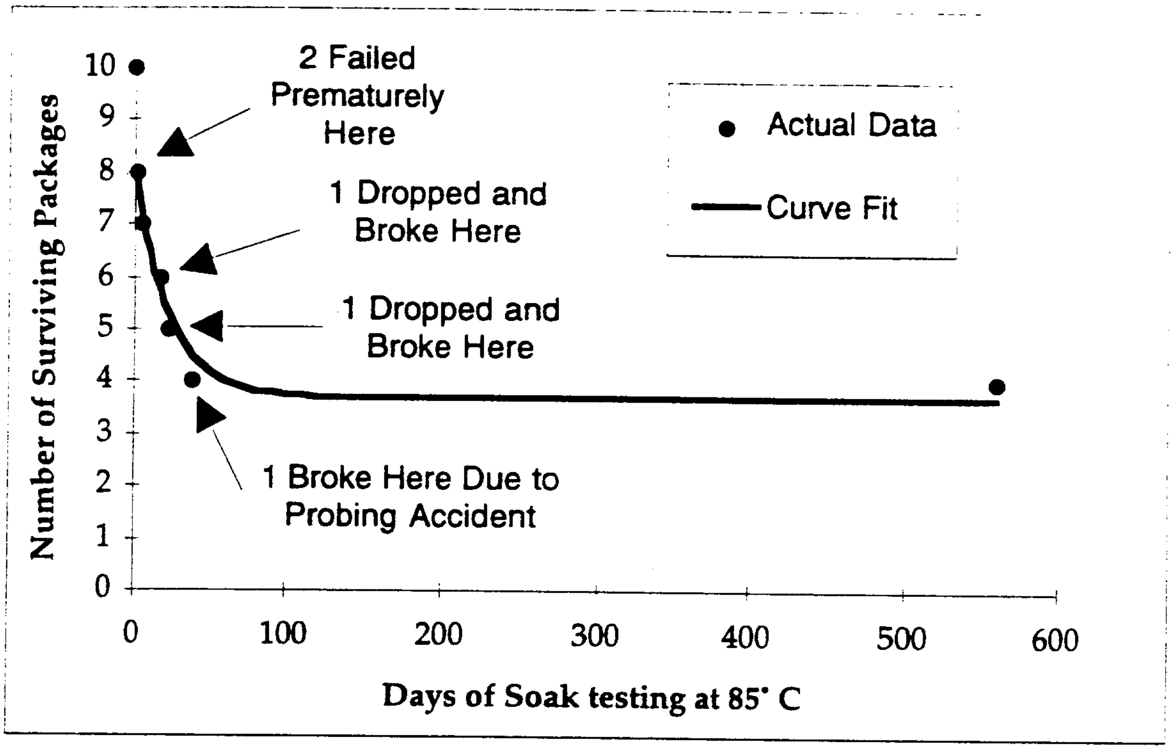

Figure 7: Summary of the lifetimes of the 10 packages which have been soak tested at 85° C in DI water.

Since the tests in 85° C are still in progress we can not accurately determine the activation energy in our tests. Also until all of the samples show leakage, we cannot obtain the MTTF at the accelerated temperatures. We can, however, obtain worst case MTTFs for the 85° C soak tests by assuming that all the remaining packages in this test show leakage today. This worst case MTTF can be used to calculate the worst case activation energy, and hence the worst case MTTF at body temperature. Performing this calculation yields:

$$MTTF|_{85°C} = 301.4\,Days \quad MTTF|_{95°C} = 118.7\,Days$$

Q=1.06eV, AF(95°C)=513.6, AF(85°C)=202.3

$$MTTF|_{37°C} = 167\,Years$$

We call this average lifetime at body temperature of 167 years the worst case lifetime because every extra day that the remaining 85° C packages last increases this projected lifetime. Also, it should be noted that we have included every single sample in the 85°C and 95°C soak tests in this calculation except the 15% which failed in the first day (we assume that these early failures can be screened for). However some of these capsules failed due to mishandling during testing, rather than due to actual leakage of the package. If we disregard the samples that we have attributed failure due to mishandling, we obtain a somewhat longer mean time to failure:

$$MTTF|_{85°C} = 466.4\ Days \quad MTTF|_{95°C} = 135.7\ Days$$

Q=1.40eV, AF(95°C)=3856, AF(85°C)=1124

$$MTTF|_{37°C} = 1433\ Years$$

The above activation energy of 1.40eV is larger than what we expect for these packages and hence the MTTF value is also higher than the previous values calculated in this report. In either case it is obvious that the expected lifetime of these packages in DI water is very long. Also, as expected the MTTF in DI water is longer than that in a saline environment.

An interesting result evident from both of these calculations is that the activation energy is indeed higher in DI water, partly because the tests have been running for a longer time, and partly because the effects of dissolution are minimized in DI water. This supports our theory, stated in the previous section, that the lower activation energy in saline tests is lower due to dissolution. Additional tests are needed to verify this.

2.1.5 Ongoing Room Temperature Soak Tests

We have also continued our soak tests in phosphate buffered saline at room temperature. Table 6 below lists some of the pertinent data from these soak tests. These tests have been started as a control study independent of our accelerated tests. We have observed that at room temperature we are below the activation energy required to cause dissolution of the substrate and the deposited films and as such we do not observe any dissolution related failures. We had 4 packages that were being tested at the beginning of this quarter and during this quarter, these 4 packages have shown no sign of moisture either measured electrically or observed visually after an average of 421 days of soaking and they are still being tested. The longest going sample has reached a total of 495 days and is still going.

Table 6: Data for room temperature soak tests in saline.

Number of packages in this study	6
Soaking solution	Saline
Failed within 24 hours (not included in MTTF)	1
Longest lasting packages so far in this study	495 days
Packages still under tests with no measurable room temperature condensation inside	4
Average lifetime to date (MTTF)	*421 days*

2.1.6 Failure Analysis of the Samples

We have carefully examined the bonding surface of the samples that have leaked throughout our accelerated tests. For instance, of the 4 samples that have failed during the past quarter, we have found one or more leakage paths in all of the samples. A typical one of these paths is shown in Figure 8 for a sample that has leaked after soaking for 191 days in saline solution at 85°C. We attribute this failure to the dissolution of polysilicon layer under the glass capsule. In order to further investigate this matter, we have taken a silicon substrate (with no glass capsule) and have soaked it with one of our other samples for a total of 139 days in saline at 95°C. The optical photograph in Figure 9 shows that some of the areas have been discolored, most likely due to dissolution. It can also be seen that some of the polysilicon feedthrough lines have been attacked. The sample was then diced along the arrow direction (perpendicular to the feedthroughs) shown in the same figure.

A SEM photograph of the cross section along the cleaved area has been taken after the sample is diced. Figure 10 indicates that indeed the polysilicon feedthrough lines have been attacked. We do not quite know why, as these lines are supposed to be protected from the solution at all times by the dielectrics from the top and the metal in the stimulating electrode areas or the bonding pad regions. It is clear that the dielectrics on top of the feedthrough lines are not attacked. Therefore, the only conclusion we can draw from this is that hot saline attacks the polysilicon lines in the region of the bonding pads/sites and slowly etches the polysilicon lines. It is hard to believe that such a long length of the polysilicon feedthrough lines can be etched by saline, but at this point this seems to be the only reasonable conclusion that can be drawn from these preliminary tests. some of the possible paths for moisture penetration into the package. We have also examined various other sections of this sample and found evidence for the same trend.

A second sample that has failed after 129 days in saline solution at 85°C is also analyzed. The optical photograph in Figure 11 shows the leakage path and also the corrosion related discoloration. This sample is diced along the arrow direction and then cleaned. Later we have taken SEM photographs of the interface between the glass capsule and the silicon substrate. We have also examined this sample thoroughly under the SEM. Figure 12 shows a photograph of the area indicating the cause of the failure for this device. It is clear that saline has attacked the polysilicon layer and has exposed the PSG film, which is also partially attacked in saline.

It should be mentioned again that all of these tests were performed at 95°C, and that is primarily why silicon dissolution has become such an important problem. At lower temperatures these problems will be far less serious. These tests also indicate that one should pay closer attention to film dissolution in salt water environments. This was previously indicated and discovered by our colleagues (S. Cogan at EIC Lab, and D. Edell at MIT Lincoln Lab). We need to determine how severe of a problem this will be at body temperatures. To do this, the activation energies and reactions rates at lower temperatures need to be determined. Some of these values have been determined by other investigators, and some remain to be measured.

It is also possible to significantly slow down the dissolution process by either coating the polysilicon regions with another film (either a polymeric film like silicone, or a deposited film like silicon dioxide), and or prevent chemical dissolution by biasing the polysilicon layers at an appropriate voltage. It should be noted that polysilicon is in contact with the solution while being shorted to an iridium film, which is also ion contact with the solution. This sets up an electrochemical cell which could contribute to the enhanced dissolution of the polysilicon film. All of these techniques will be considered and measurements will be done in the next few quarters to determine dissolution rates at body temperature.

Figure 8: Optical photograph showing the leakage path of a sample soaked for 191 days in saline solution.

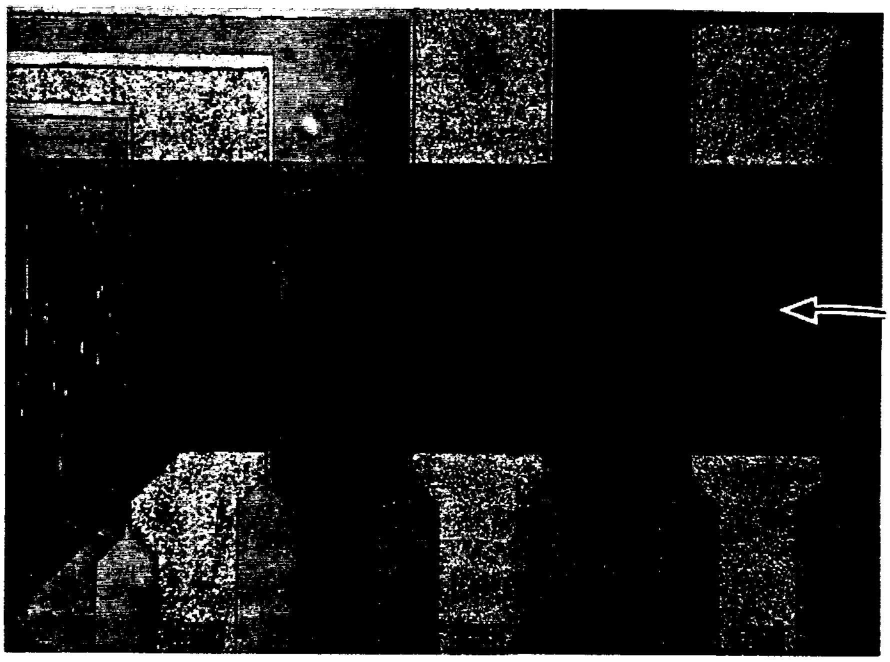

Figure 9: The photograph showing discoloration over the exposed bonding surface of a Silicon substrate soaked for 139 days in saline solution.

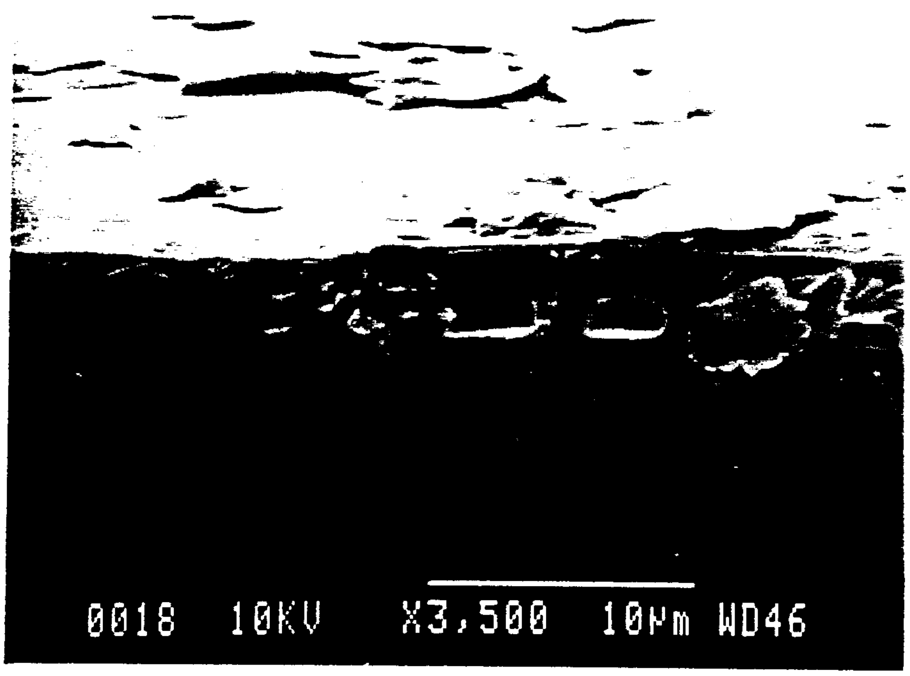

Figure 10: A SEM photograph showing the cross section of the sample soaked in saline.

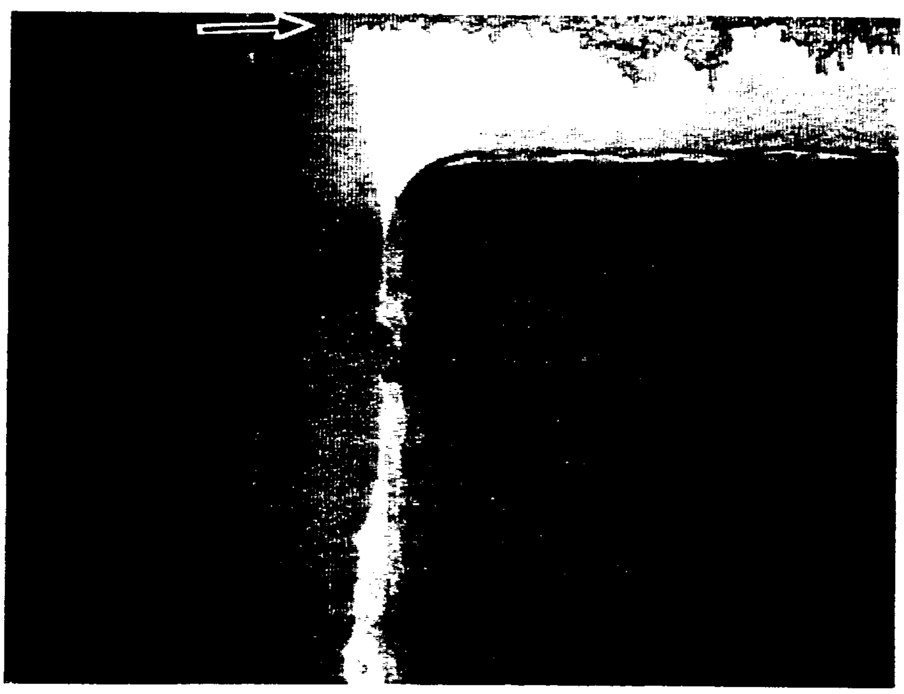

Figure 11: The leakage path of a sample after being soaked for 129 days in saline solution.

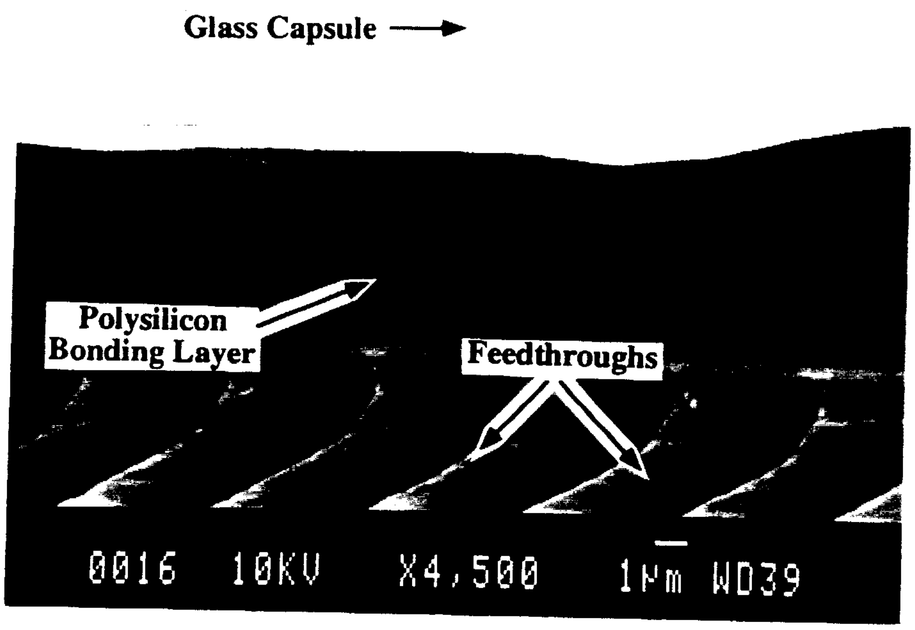

Figure 12: The SEM photograph showing the glass to silicon interface.

1.1.7 In-Vivo Tests

This quarter we sent 7 packages to our colleagues at Hines VA Hospital in Hines, Illinois (Dr. James Walter). These packages were made from the ultrasonically machined glass capsules and the silicon package substrates containing stimulating. The packages were, therefore, an exact mockup of what will be eventually used for functional microstimulators for animal studies. These devices were implanted into the bladder wall of rats and were later explanted after one month. The early observation by the VA team is that all of the devices looked very good after explantation, lying in a thin (<0.1mm) connective tissue sheath. One of these devices was covered with silastic before the implant as seen in Figure 13. Before being sent to us, these microstimulators were placed in formalin for three days and later placed in distilled water. The VA team also reports that none of these devices migrated and only one suture was found through the bladder wall. The microstimulators did not adhere to the skin and simply came out of their pouch after cutting a slit with a scalpel. The photograph in Figure 13 below shows the state of the devices after we received them. As seen in the figure, all of the devices remained intact after being explanted. In the past, the devices often broke during surgical removal due to the thin silicon substrate. One of the encouraging results of these tests is that the packages made from the thicker silicon substrate are more robust than the previous packages made with thinned silicon substrates.

After receiving the packages from the VA team, we cleaned the residue from over them and then inspected the polysilicon bonding surface through the glass from the top. There was no indication of a leakage path. We also soaked the devices for 2 days in DI water at 95°C and afterwards, when we examined them , we did not observe any indication of moisture inside the packages. Figure 14 shows a typical area on the bonding surface which indicates that no corrosion or leakage paths have occurred during the duration of the implant. Moreover, we broke one of these packages by removing the glass capsule and looked for any evidence of moisture or stains inside the package. The structures inside the package, namely the dew point sensors and various other metal lines, had no stains and/or discoloration from moisture penetration into the package which are typical of leaked packages. With this evidence we are very positive that our packages not only stayed intact, but also were hermetic for the duration of the implant.

We also carefully inspected the packages under a scanning electron microscope. We have focused on the electrodes and the various metal lines that are exposed to body fluids. None of these areas showed any sign of damage. We also closely observed the interface between the glass capsule and the silicon substrate for any evidence of dissolution and/or corrosion. No dissolution or corrosion was observed. Admittedly these tests were very short term tests and the results cannot be used to conclusively verify package hermeticity in biological environments, and its biocompatibility. However, the tests clearly indicate that the packages do possess sufficient mechanical strength and do not appear to cause any adverse reactions in the tissue. We will continue to furnish the VA team with additional packages for further longer term tests. We will continue to report on our in-vivo tests both at the VA Hospital and at Vanderbilt University.

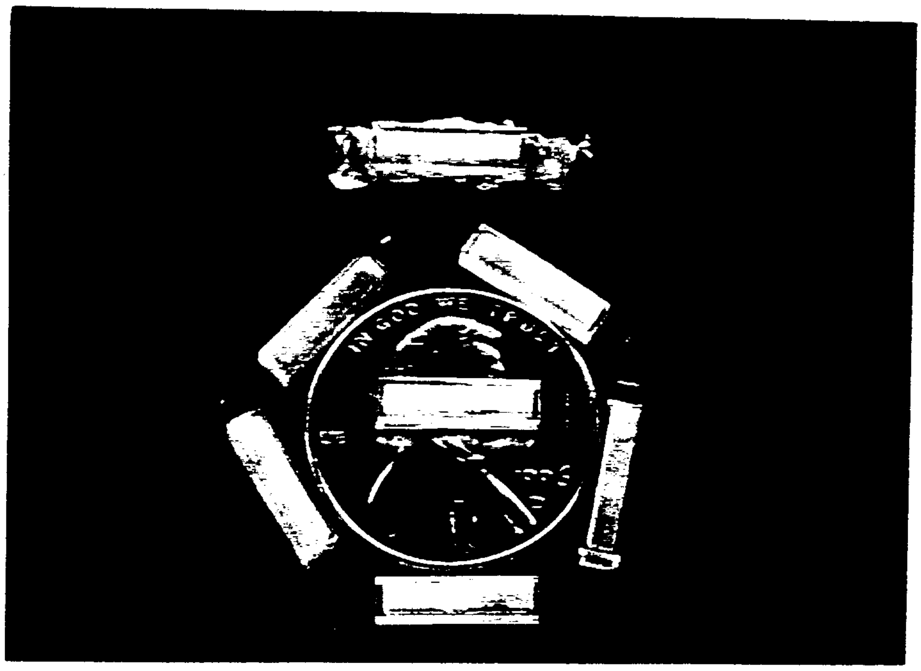

Figure 13: An overall view of the devices after explantation.

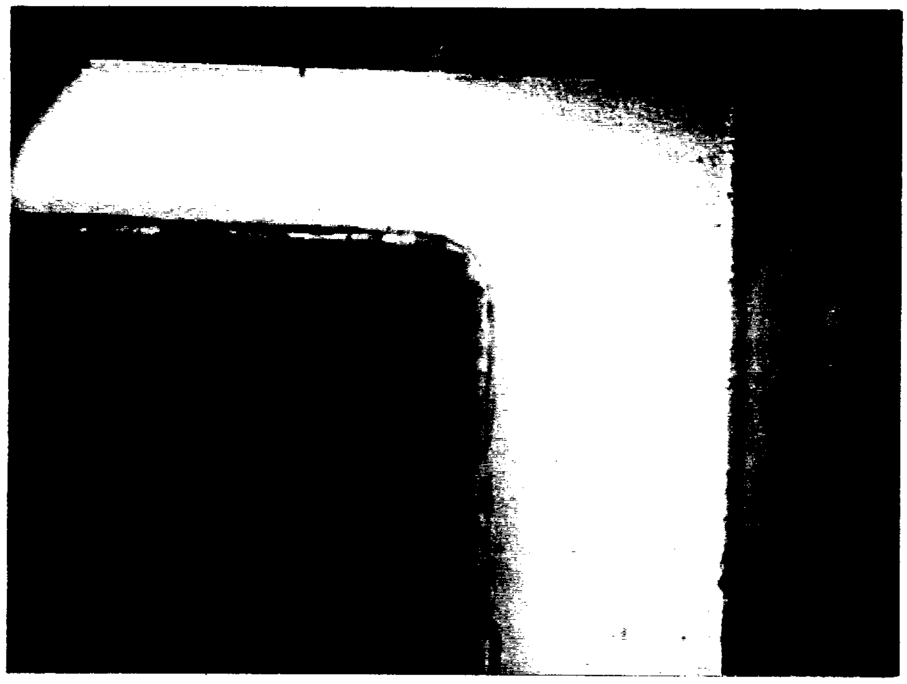

Figure 14: A typical region of the bonding surface indicating the absence of any leakage paths and related dissolution.

2.2 Implantable Microstimulators

This quarter, work on the microstimulator circuitry has focused on the preparation of assembled microstimulators for delivery, and the improvement of certain features of the circuitry to make the overall system more reliable and less power hungry. As mentioned in the previous quarter's report, there are several investigators that are eager to collaborate with us in carrying out *in vivo* tests of fully assembled microstimulators. Also mentioned in the previous report was the difficulty that we have encountered in reliably powering the microstimulators within the full volume of medium to larger diameter transmitter coils (9cm diameter and above). The commencement of *in vivo* tests and the implementation of these various improvements in the microstimulator circuitry (both single-channel and multichannel generations) will be among the principal objectives of the coming quarter.

Presently we have a few assembled microstimulators that are either fully working or still being tested to confirm functionality after assembly. Once functionality on these units is verified through telemetric testing, these units will be encapsulated. They will then be ready for delivery. We are in the process of preparing external telemetry transmitter units to accompany these devices. We expect to be able to begin *in vivo* tests in the coming quarter.

The first generation of delivered microstimulators will be encapsulated in medical grade silicone rubber. This should protect the devices well enough to allow preliminary shorter term tests in live subjects. Furthermore, though the silicone adhesive is not in itself sterile, the unit can be sterilized easily using an autoclave or other routine methods. Encapsulation in silicone rubber is only a temporary method made necessary because of difficulty encountered in reception of adequate power through the telemetric link. We have succeeded in operating assembled microstimulators within roughly 30-40% of the volume of a 9cm diameter transmitter coil, the portion within about 2cm of the edge of the coil. Clearly we would like to extend the usable volume of the transmitter coil to 100%, and we are striving toward that objective. This will enable the more reliable usage of a single device and even the use of multiple, individually addressed devices placed anywhere within the coil. In order to achieve the current results we have found it necessary to use a receiver coil (microwelded on-chip) that is about 1.5-1.75mm in diameter and thus does not fit inside the current glass capsule. It would be preferable to use the 1.25mm diameter receiver coils, as it was already shown in a previous quarter report that this diameter coil fit nicely inside an electrostatically bonded package and that the insulation of the coil did not seem to degrade from the high temperatures experienced in the bonding process.

We are currently taking two approaches toward solving this problem of inadequate power delivery to the microstimulators. Rigorous modeling of the telemetry link has given us a very close correspondence between expected and actual received power. Thus we are working to improve the strength of our link by analytical modeling, taking into account such constraints as the smaller diameter receiver coil. Thus far some combinations seem favorable as suggested by the model, and we are in the process of trying these modifications to optimize the telemetry link. We expect to have a clearer idea of how well our model predicts reality in the case of our weak telemetric link very soon. Of course, even if the results are not ideal, this will be a useful realization since it will indicate to us that we must seek and include certain other factors in our model.

The other approach involves a redesign of certain parts of the current microstimulator circuitry, to make the circuit use less power in general. There are several areas in which relatively slight modifications may dramatically improve the reliability of the Microstimulator when operated by a realistic, weakly coupled link. The voltage regulation circuitry on the current single-channel devices, for instance, consumes considerable current in order to adequately bias the Zener diodes that provide the voltage references. In fact, these diodes are essentially overdriven in the current design, originally a design consideration to provide a safety margin since the Zener diodes were not well characterized at the time of the last design and fabrication run. Due to this regulation block alone, the input current of the single-channel microstimulator is virtually a linear function of the received input voltage, and this block consumes about 2mA or more of current at 18-20V received voltage levels. We now know that our Zener diode process is well-defined and predictable, and we know that the Zener diodes could be biased with roughly 20% to 50% of the current now provided. To do so requires precise current sources that are reasonably independent of the received voltage (above a certain minimal operating level). The multi-channel design accomplishes this through MOS current mirrors, and it is an optimized version of this design that we intend to incorporate on a slightly modified single-channel microstimulator. Indeed, several sub-blocks of the multichannel microstimulator can be fairly easily modified and incorporated into the single-channel unit to achieve a very substantial reduction in operating power. We are currently testing these sub-blocks to characterize them fully and to determine what modifications will need to be made to enable their use with the single-channel system. Theoretically, the multichannel microstimulator's envelope detector could be modified to use as little as 25% of the single-channel device's current envelope detector. The clock could also be modified to use a predicted 40% or less of the power consumed by the previous single-channel microstimulator's clock design. Along with power savings, considerable chip area savings may be achieved as well.

Changes are also being studied and considered for the stimulus current generator block of the single-channel microstimulator. In some tests performed telemetrically, as documented in last quarter's report, the stimulus current was not as uniform or as close to the expected 10mA as desired. In fact, it was found that when driving loads as low as 270-560Ω at received voltage levels of 18V maximum, the stimulus current could be as much as about 40-50% higher than expected. It was also found that the stimulus current could deviate below the expected 10mA, predictably so when the compliance voltage was not adequate (i.e. the 8V supply was too weak due to low received voltage). The only surprise in this last result is that the 8V supply voltage seemed weaker than it should have been for a given telemetrically received voltage (when compared to results obtained by applying a DC voltage of the same magnitude at the input single-endedly). These results should be confirmed with other samples, however, before drawing definitive conclusions. Nonetheless, this is further reason to replace the single-channel microstimulator's voltage regulator portion with a less power-hungry version so that the supplies will work more strongly at the desirable 13-18V received voltage levels.

These are all changes that we are in the process of simulating and making with the intent of fabricating a corrected, more reliable single-channel microstimulator during the coming quarter. Minor changes are also planned to certain parts of the multichannel microstimulator. In the meantime, we will proceed to assemble, test, and deliver silicone encapsulated units to our collaborating investigators so that much anticipated *in vivo* tests can begin. Additionally, if our modeling of the telemetric link proves accurate, it will be possible to deliver units that utilize the smaller diameter receiver coils and are glass encapsulated.

3. ACTIVITIES PLANNED FOR THE COMING QUARTER

Work on the various aspects of the project will continue this coming quarter, with most of the emphasis placed on starting additional soak tests, and on trying to fabricate more functional microstimulators. Our primary goal is to address the issue of silicon dissolution in saline at high temperatures. To do this we need additional silicon substrates, which are almost ready. The fabrication of these substrates will be completed in a few weeks and we will begin a new set of tests at different elevated temperatures. In order to overcome the dissolution problem the simplest approach is to coat the sensitive areas with silicone to avoid their direct exposure to saline. This will be done with the new substrates. Ideally we prefer to avoid the use of silicones for both practical reasons and because we need to make sure that any measured data for hermeticity is truly representative of the package and not of any other materials used in carrying out the soak tests. We are exploring different ideas to address this issue, including the use of techniques to retard dissolution electrochemically, and depositing other thin films that prevent dissolution. All of these will be pursued as we continue with our soak tests.

The second area of importance for us is the fabrication and assembly of prototypes of the single-channel microstimulator and its delivery to interested users. We have a number of investigators who have expressed interest in receiving and testing these devices and we are exerting our best efforts to provide the microstimulators so that we can obtain in-vivo results for the first time from these devices. During the past quarter we performed additional analysis on our telemetry link to deliver sufficient power to the microstimulator anywhere within the volume of a 9cm diameter coil. In the coming quarter we will optimize the design of the transmitter coil to accomplish this. We will also modify the design of the receiver circuitry to reduce its power dissipation which is the main cause of the problem. In either case, we believe that we will have a few sample devices that we can deliver to interested users for testing in biological environments.